

CLAIMS

What is claimed is:

1. A lipid-based dispersion comprising, a) phosphatidyl choline; b) an anionic phospholipid; optionally c) up to 1% cholesterol by weight of total lipids; and optionally d) a therapeutic agent; wherein the mean particle size measured by dynamic light scattering is less than 100 nm.
2. The lipid-based dispersion of claim 1 wherein at least about 60% of the fatty-acid chains of the phosphatidyl choline comprise 16 or more carbon atoms.
3. The lipid-based dispersion of claim 1 wherein at least about 70% of the fatty-acid chains of the phosphatidyl choline comprise 16 or more carbon atoms.
4. The lipid-based dispersion of claim 1 wherein at least about 80% of the fatty-acid chains of the phosphatidyl choline comprise 16 or more carbon atoms.
5. The lipid-based dispersion of claim 1 wherein at least about 90% of the fatty-acid chains of the phosphatidyl choline comprise 16 or more carbon atoms.
6. The lipid-based dispersion of claim 1 wherein at least about 60% of the fatty-acid chains of the phosphatidyl choline comprise 18 or more carbon atoms.
7. The lipid-based dispersion of claim 1 wherein at least about 70% of the fatty-acid chains of the phosphatidyl choline comprise 18 or more carbon atoms.
8. The lipid-based dispersion of claim 1 wherein at least about 80% of the fatty-acid chains of the phosphatidyl choline comprise 18 or more carbon atoms.
9. The lipid-based dispersion of claim 1 wherein at least about 90% of the fatty-acid chains of the phosphatidyl choline comprise 18 or more carbon atoms.
10. The lipid-based dispersion of any one of claims 1-9 wherein at least 50%

of the fatty-acid chains of the phosphatidyl choline comprise at least one double bond.

11. The lipid-based dispersion of any one of claims 1-9 wherein at least 60%
5 of the fatty-acid chains of the phosphatidyl choline comprise at least one double bond.

12. The lipid-based dispersion of any one of claims 1-9 wherein at least 75%
10 of the fatty-acid chains of the phosphatidyl choline comprise at least one double bond.

13. The lipid-based dispersion of claim 1 wherein the phosphatidyl choline is selected from Soy-PC, Egg-PC, DEPC, and DOPC.

14. The lipid-based dispersion of claim 1 wherein the phosphatidyl choline is Soy-PC.
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15. The lipid-based dispersion of claim 1 wherein the phosphatidyl choline is Egg-PC.
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16. The lipid-based dispersion of any one of claims 1-15 that comprises less than 0.5% cholesterol.

17. The lipid-based dispersion of any one of claims 1-15 that comprises less
25 than 0.05% cholesterol.

18. The lipid-based dispersion of any one of claims 1-15 that comprises no cholesterol.

19. The lipid-based dispersion of any one of claims 1-18 wherein at least
30 about 60% of the fatty-acid chains of the anionic phospholipid comprise 14 or more carbon atoms.

20. The lipid-based dispersion of any one of claims 1-18 wherein at least about 70% of the fatty-acid chains of the anionic phospholipid comprise 16 or more carbon atoms.
- 5 21. The lipid-based dispersion of any one of claims 1-18 wherein at least about 80% of the fatty-acid chains of the anionic phospholipid comprise 16 or more carbon atoms.
22. The lipid-based dispersion of any one of claims 1-18 wherein at least
10 about 90% of the fatty-acid chains of the anionic phospholipid comprise 16 or more carbon atoms.
23. The lipid-based dispersion of any one of claims 1-18 wherein at least
15 about 60% of the fatty-acid chains of the anionic phospholipid comprise 18 or more carbon atoms.
24. The lipid-based dispersion of any one of claims 1-18 wherein at least about 70% of the fatty-acid chains of the anionic phospholipid comprise 18 or more carbon atoms.
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25. The lipid-based dispersion of any one of claims 1-18 wherein at least about 80% of the fatty-acid chains of the anionic phospholipid comprise 18 or more carbon atoms.
- 25 26. The lipid-based dispersion of any one of claims 1-18 wherein at least about 90% of the fatty-acid chains of the anionic phospholipid comprise 18 or more carbon atoms.
27. The lipid-based dispersion of any one of claims 1-18 wherein the anionic
30 phospholipid is selected from Egg-PG, Soy-PG, DSPG, DPPG, DEPG, DOPG, DSPA, DPPA, DEPA, DOPA, DSPS, DPPS, DEPS, and DOPS, and mixtures thereof.

28. The lipid-based dispersion of any one of claims 1-18 wherein the anionic phospholipid is DSPG.
29. The lipid-based dispersion of any one of claims 1-28 which comprises a
5 therapeutic agent.
30. The lipid-based dispersion of claim 29 wherein the therapeutic agent is an analgesic, anesthetic, antiacne agent, antibiotic, antibacterial, anticholinergic, anticoagulant, antidyskinetic, antifibrotic, antifungal, antiglaucoma agents, anti-
10 inflammatory, antineoplastic, antiosteoporotic, antipagetic, anti-Parkinson's agent, antipsoriatic, antipyretic, antiseptic, antithrombotic, calcium regulator, keratolytic, an immunosuppressant, a photoreactive agent, or a sclerosing agent.
31. The lipid-based dispersion of claim 29 wherein the therapeutic agent is
15 benzocaine, bupivacaine, chlorprocaine, epinephrine, etidocaine, levobupivacaine, lidocaine, midazolam, oxycondone, phencyclidine, propofol, ropivacaine, 6-diazo-5-oxo-L-norleucine, allopurinol sodium, azaserine, carzinophillin A, denopterin, dolasetron mesylate, edatrexate, eflornithine, erythropoietin, etoposide, fluconazole, melphalan, methotrexate, mycophenolic
20 acid, pamidronate disodium, podophyllinic acid 2-ethylhydrazide, paclitaxel, pteropterin, streptonigrin, Tomudex® (N-((5-(((1,4-Dihydro-2-methyl-4-oxo-6-quinazoliny)methyl)methylamino)-2-thienyl)carbonyl)-L-glutamic acid), ubenimex, azathioprine, basiliximab, bucillamine, cyclosporine, daclizumab, muromonab-CD3, mycophenolic acid, mycophenolate mofetil, procodazole,
25 Rh₀(D) immune globulin (human), romurtide, sirolimus, ubenimex, acetaminophen, aspirin, hydrocodone, pentosan polysulfate sodium, phenyl salicylate, erythromycin, isotretinoin, tretinoin, amikin sulfate, azithromycin, cefazolin, cilastatin, imipenem, minocycline, penicillin, 4-sulfanilamidosalicylic acid, acediasulfone, amfenac, amoxicillin, ampicillin, apalcillin, apicycline,
30 aspoxicillin, aztreonam, bambermycin(s), biapenem, carbenicillin, carumonam, cefadroxil, cefamandole, cefatrizine, cefbuperazone, cefclidin, cefdinir, cefditoren, cefepime, cefetamet, cefixime, cefmenoxime, cefminox, cefodizime, cefonicid, cefoperazone, ceforanide, cefotaxime, cefotetan, cefotiam,

- cefozopran, cefpimizole, cefpiramide, cefpirome, cefprozil, cefroxadine, ceftazidime, ceftoram, ceftibuten, ceftriaxone, cefuzonam, cephalixin, cephaloglycin, cephalosporin C, cephradine, ciprofloxacin, clinafloxacin, cyclacillin, enoxacin, epicillin, flomoxef, grepafloxacin, hetacillin, imipenem,
- 5 lomefloxacin, lymecycline, meropenem, moxalactam, mupirocin, nadifloxacin, norfloxacin, panipenem, pazufloxacin, penicillin N, pipemidic acid, quinacillin, ritipenem, salazosulfadimidine, sparfloxacin, succisulfone, sulfachrysoidine, sulfaloxic acid, teicoplanin, temafloxacin, temocillin, ticarcillin, tigemonam, tosfloxacin, trovafloxacin, vancomycin, hyoscyamine, oxybutynin, dalteparin,
- 10 heparin, warfarin, amantidine, haloperidol, tetrabenazine, aprotinin, desmopressin acetate, amphotericin B, azaserine, candicidin(s), itraconazole, lucensomycin, natamycin, nystatin, brimonidine tartrate, brinzolamide, demecarium bromide, levobetaxolol, a glucocorticoid, gold sodium thiomalate, 3-amino-4-hydroxybutyric acid, aceclofenac, alminoprofen, bromfenac,
- 15 bumadizon, carprofen, diclofenac, diflunisal, enfenamic acid, etodolac, fendosal, flufenamic acid, gentisic acid, meclofenamic acid, mefenamic acid, mesalamine, niflumic acid, olsalazine oxaceprol, S-adenosylmethionine, salsalate, sulfasalazine, tolfenamic acid, raloxifene, sodium fluoride, and teriparatide acetate, elcatonin, tiludonic acid, benztropine mesylate, biperiden, acitretin,
- 20 anthralin, lonapalene, tacalcitol, tazarotene, acetaminosalol, bermoprofen, epirizole, morazone, salacylamide, chlorhexidine gluconate, metronidazole, sodium sulfacetamide, argatroban, daltroban, iloprost, lamifiban, ozagrel, ridogrel, taprostene, tirofiban, calcifediol, calcitonin, ipriflavone, parathyroid hormone, imiquimod, podofilox, podophyllin, polidocanol, sodium ricinoleate,
- 25 sodium tetradecyl sulfate, or tribenoside.

32. The lipid-based dispersion of claim 29 wherein the therapeutic agent is etoposide, propofol, cyclosporin, or paclitaxel.

- 30 33. The lipid-based dispersion of claim 29 wherein the therapeutic agent is gallium deuteroporphyrin dimethyl ester.

34. The lipid-based dispersion of any one of claims 1-33 that comprises liposomes.
35. The lipid-based dispersion of claim 34 wherein the liposomes have a melting temperature below 35 °C.
36. The lipid-based dispersion of claim 34 wherein the liposomes have a melting temperature below 25 °C.
37. The lipid-based dispersion of claim 34 wherein the liposomes have a melting temperature below 15 °C.
38. The lipid-based dispersion of any one of claims 1-37 which comprises from 0.05 to 60 % anionic phospholipid by mole relative to phosphatidyl choline.
39. The lipid-based dispersion of any one of claims 1-38 wherein the weight ratio of total lipid (phosphatidyl choline + anionic phospholipid) to therapeutic agent is greater than 1:1.
40. The lipid-based dispersion of any one of claims 1-38 wherein the weight ratio of total lipid (phosphatidyl choline + anionic phospholipid) to therapeutic agent is greater than 5:1.
41. The lipid-based dispersion of any one of claims 1-38 wherein the weight ratio of total lipid (phosphatidyl choline + anionic phospholipid) to therapeutic agent is greater than 10:1.
42. The lipid-based dispersion of any one of claims 1-38 wherein the weight ratio of total lipid (phosphatidyl choline + anionic phospholipid) to therapeutic agent is greater than 20:1.

43. A unit dosage form comprising a lipid-based dispersion of any one of claims 1-42.
44. The unit dosage form of claim 43, which is formulated for parenteral
5 administration.
45. The unit dosage form of claim 43, which is formulated for oral administration.
- 10 46. A method for modulating the solubility of a therapeutic agent comprising incorporating the agent in a lipid-based dispersion as described in any one of claims 1-42.
- 15 47. A method for producing an anesthetic or sedative effect in an animal comprising administering to the animal an effective amount of a lipid based dispersion as described in any one of claims 1-42 wherein the therapeutic agent is an anesthetic or a sedative.
- 20 48. The method of claim 47 wherein the therapeutic agent is propofol.
49. A method for producing an antineoplastic effect in an animal comprising administering to the animal an effective amount of a lipid based dispersion as described in any one of claims 1-42 wherein the therapeutic agent is an antineoplastic agent.
- 25 50. The method of claim 49 wherein the antineoplastic agent is etoposide.
51. The method of claim 49 wherein the antineoplastic agent is paclitaxel.
- 30 52. A method for producing an immunosuppressive effect in an animal comprising administering to the animal an effective amount of a lipid based dispersion as described in any one of claims 1-42 wherein the therapeutic agent is an immunosuppressive agent.

53. The method of claim 52 wherein the immunosuppressive agent is cyclosporine.
- 5 54. A method for treating atherosclerosis, atherosclerotic vulnerable plaque or restenosis, or a combination thereof, in an animal, comprising administering to the animal an effective amount of a lipid based dispersion as described in any one of claims 1-42 wherein the therapeutic agent is a photoreactive agent.
- 10 55. The method of claim 54, wherein the photoreactive agent is gallium deuteroporphyrin dimethyl ester.
56. The method of claim 54 wherein the photoreactive agent is gallium deuteroporphyrin dimethyl ester and wherein the lipid dispersion comprises Soy
15 PC and DSPG in a mole ratio of 1:0.1 to 1:0.4 Soy PC:DSPG.54.
57. A lipid-based dispersion as described in any one of claims 1-42 for use in medical therapy.
- 20 58. The use of a lipid based dispersion as described in any one of claims 1-32 and 34-42 wherein the therapeutic agent is an anesthetic or a sedative to prepare a medicament useful for producing an anesthetic or sedative effect in a mammal.
59. The use of claim 58 wherein the therapeutic agent is propofol.
- 25 60. The use of a lipid based dispersion as described in any one of claims 1-32 and 34-42 wherein the therapeutic agent an antineoplastic agent, to prepare a medicament useful for producing an antineoplastic effect in a mammal.
- 30 61. The use of claim 60 wherein the antineoplastic agent is etoposide.
62. The use of claim 60 wherein the antineoplastic agent is paclitaxel.

63. The use of a lipid based dispersion as described in any one of claims 1-32 and 34-42 wherein the therapeutic agent is an immunosuppressant to prepare a medicament useful for producing an immunosuppressant effect in a mammal.
- 5 64. The use of claim 63 wherein the immunosuppressant is cyclosporine.